

Research and Special Programs Administration 400 Seventh Street, S.W. Washington, D.C. 20590

APR 26 1000

Mr. Andrew N. Romach
Regulatory Compliance Manager
Radian International
Post Office Box 13000
Research Triangle Park, North Carolina 27709

Dear Mr. Romach:

This is in response to your letter of March 4, 1999, requesting clarification on the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) as they pertain to the transportation of a Magnetic Resonance Imaging (MRI) Magnet machine by highway. You state that the MRI machine contains helium, refrigerated liquid as a refrigerant to keep the system at a low temperature during transit. Specifically, you ask whether the machine qualifies as a "process system" under the provisions in 49 CFR § 173.320(b)(2).

Based on the information you provided, the answer is yes. The machine qualifies as a process system and, as provided by § 173.320(b)(2), is not subject to the requirements in 49 CFR Parts 171-180.

Sincerely,

Hattie L. Mitchell, Chief

Regulatory Review and Reinvention

Office of Hazardous Materials Standards



990056



March 4, 1999

Mr. Ed Mazzullo, Director
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Dear Mr. Mazzullo:

On behalf of GE Medical Systems Group, I am writing to you to request a written regulatory interpretation concerning the applicability of 49 CFR §173.320(b)(2) to the transport of Magnetic Resonance Imaging (MRI) Magnets by ground transportation. This provision reads as follows:

(b)(2) The requirements of this subchapter do not apply to atmospheric gases and helium: When used in operation of a process system; such as a refrigeration system (pressure may exceed 25.3 psig).

I have attached copy of a written interpretation from you addressed to Mr. Roy J. Miller, Hospital Support Service, Ltd., dated July 18, 1990. In this letter you stated that the "Magnetic Resonance Imaging Magnet and a Balzer Cryogenic Refrigerator System" would qualify "as a process system, as provided by \$173.320(b)(2)."

As described on page 2 of the original application submitted by Mr. Miller (also attached), the MRI contained in Hospital Support Service Ltd's mobile laboratory is manufactured by GE Medical Systems Group. GE Medical Systems Group currently manufactures this same type of magnet and frequently ships it by truck from our manufacturing facility directly to the hospital for immediate installation and use. Our magnet is similar to the magnet contained in the mobile unit. It contains a comparable amount of refrigerated liquid helium, which is functioning in the same manner as described in the original application to keep the magnet cold during shipment. In our particular case, the MRI is not operating during transit. However, in both scenarios during transit, the refrigeration system containing the liquefied refrigerated helium that is integral to the MRI does continue to maintain a very low temperature to ensure that the MRI will operate properly once it reaches its destination.

Would the MRI manufactured by GE Medical Systems qualify as a "process system" for purposes of ground transportation and be able to take advantage of the exception provided in 49 CFR §173.320(b)(2)?

If you have any questions concerning this request, please call me directly at (919) 461-1220.

Sincerely,

Andrew N. Romach

Regulatory Compliance Manager

Radian International

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